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| APPLICATION NO.                  | FILING DATE                       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-----------------------------------|----------------------|---------------------|------------------|
| 10/561,793                       | 06/09/2006                        | Guy Vancanneyt       | 58764.000055        | 3642             |
| 21967<br>HUNTON & W              | 7590 06/12/200<br>YILLIAMS LLP    | EXAMINER             |                     |                  |
| INTELLECTUAL PROPERTY DEPARTMENT |                                   |                      | ZHENG, LI           |                  |
| SUITE 1200                       | 1900 K STREET, N.W.<br>SUITE 1200 |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20006-1109        |                                   |                      | 1638                |                  |
|                                  |                                   |                      |                     |                  |
|                                  |                                   | MAIL DATE            | DELIVERY MODE       |                  |
|                                  |                                   |                      | 06/12/2008          | PAPER            |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary  |  | Application No.  | Applicant(s)                    |  |  |  |
|--|--|--|---------------------------------|--|--|--|
|  |  | 10/561,793   | VANCANNEYT ET AL.               |  |  |  |
|  |  | Examiner   | Art Unit                        |  |  |  |
|  |  | LI ZHENG   | 1638                            |  |  |  |
|  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |                                 |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |  |                                 |  |  |  |
| Status   |  |  |                                 |  |  |  |
| 1) 又   | Responsive to communication(s) filed on <u>07 M</u>  | arch 2008.   |                                 |  |  |  |
| •  |  | action is non-final.   |                                 |  |  |  |
|  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |                                 |  |  |  |
| /—   | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |                                 |  |  |  |
| Dispositi  | on of Claims   |  |                                 |  |  |  |
| 4)⊠ Claim(s) <u>1,2,15-17,24 and 27</u> is/are pending in the application.   |  |  |                                 |  |  |  |
| -  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |                                 |  |  |  |
| 5) Claim(s) is/are allowed.  |  |  |                                 |  |  |  |
| 6)⊠ Claim(s) <u>1,2,15-17,24 and 27</u> is/are rejected.   |  |  |                                 |  |  |  |
| 7)   | Claim(s) is/are objected to.   |  |                                 |  |  |  |
| 8)□  | Claim(s) are subject to restriction and/or   | election requirement.  |                                 |  |  |  |
| Application Papers   |  |  |                                 |  |  |  |
| 9)   | The specification is objected to by the Examine  | r.   |                                 |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |  |  |                                 |  |  |  |
| ,  | Applicant may not request that any objection to the  |  |                                 |  |  |  |
|  | Replacement drawing sheet(s) including the correcti  | on is required if the drawing(s) is ob                                     | jected to. See 37 CFR 1.121(d). |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |  |                                 |  |  |  |
| Priority u   | ınder 35 U.S.C. § 119  |  |                                 |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |  |  |                                 |  |  |  |
| 2)  Notic<br>3)  Inforr  | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date 3/7/2008. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate                             |  |  |  |

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#### **DETAILED ACTION**

1. Claims 1-2, 15-17, 24 and 27 are pending and examined on the merits

2. Applicant's cancellations of claims 3-14, 18-23, 25-26 and 28-30 and amendments to claims 1-2, 15, 24 and 27 filed on March 7, 2008 are acknowledged.

3. The text of those sections of Title 35, U.S. Code not included in this action can

be found in a prior Office action.

4. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

## Claim Rejections - 35 USC § 103

5. Claims 1-2, 15-17 24 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yanofsky et al. (2006, U.S. Patent No. 7,135,621; '621 patent hereafter) in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed September 7, 2007. Applicants traverse in the paper filed March 7, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the references do not teach every claim limitation. More specifically, Applicants argue that '621 patent requires the use of a polynucleotide which encodes a polypeptide comprising a bHLH domain whereas claim 1 requires the "first RNA region comprises a nucleotide sequence of at least 200 consecutive nucleotides of SEQ ID NO: 1 other than a bHLH encoding region" (response, the paragraph bridging pages 11-12).

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The Office contends that although '621 teach the silencing vector comprising an antisense nucleotide sequence including bHLH domain coding region, it does not prevent a person with ordinary skill in the art from choosing a smaller fragment which does not include bHLH domain coding region for silencing IND1 homologous gene in B. napus. It is known in the art that effective siRNA could be as small as 23 bp, and that gene silencing is sequence dependent. Therefore, any fragment over 23 bp including those without bHLH domain coding region can be regarded as an obvious choice for a gene silencing vector targeting IND1 homologous genes in Brassica napus. The specification does not provide any evidence to demonstrate that using a nucleotide sequence not including bHLH domain coding region would generate unexpected result.

Applicants further argue that a person set out to modify the method of '621 patent to obtain a milder silencing of the IND genes would not turn to the Smith reference which discloses the opposite (response, page 12, 2<sup>nd</sup> paragraph).

The Office contends that the milder silencing of the instant invention is primarily achieved by using heterologous IND1 gene from Arabidopsis because of the relatively low homology between the dsRNA and endogenous gene. Although it has shown in

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Arabidopsis that hairpin structure could increase the efficiency of gene silencing, antisense and hairpin constructs are considered an obvious design choice for gene silencing. The specification suggests that to obtain desirable silencing so that pods exhibit reduced seed shattering while maintaining an agronomically relevant threshability of said pods, one could modify parameters that affect silencing, such as strength of the promoter, homology between SEQ ID NO: 1 and endogenous IND1 gene and the choice of construct. Therefore, hairpin dsRNA construct is an obvious choice in such optimization process. The Office invites Applicants to submit a 1.132 declaration disclosing unexpected results of the instantly claimed invention.

6. Claims 1-2, 15-17 24 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Liljegren et al. (2006, U.S. Patent No. 6,998,517) in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed September 7, 2007. Applicants traverse in the paper filed March 7, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present similar arguments as discussed above. Therefore, for the same reason, the rejection is maintained. The Office invites Applicants to submit a 1.132 declaration disclosing unexpected results of the instantly claimed invention.

#### **Double Patenting**

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7. Claims 1-2, 15-17 24 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yanofsky et al. (2006, U.S. Patent No. 7,135,621) in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed September 7, 2007. Applicants traverse in the paper filed March 7, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present similar arguments as discussed in the rejection under U.S.C 103 (a). Therefore, for the same reason, the rejection is maintained. The Office contends that a showing of unexpected results using the claimed invention will obviate the rejection.

8. Claims 1-2, 15-17 24 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Liljegren et al. (2006, U.S. Patent No. 6,998,517) in view Smith et al. (2000, *Nature*, 407:319-320), for the reasons of record stated in the Office action mailed September 7, 2007. Applicants traverse in the paper filed March 7, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present similar arguments as discussed in the rejection under U.S.C 103 (a). Therefore, for the same reason, the rejection is maintained. The Office contends that a showing of unexpected results using the claimed invention will obviate the rejection.

### Summary

No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/ Primary Examiner, Art Unit 1638